C-Path's PSTC Releases Points to Consider Outlining Recommendations for Analytical Validation of Assays Used in Qualifying Biomarkers

The document serves as a guide to the analysis of biomarkers in drug development

TUCSON, Ariz., June 11, 2019 — The Critical Path Institute's (C-Path) Predictive Safety Testing Consortium (PSTC) has released a new consensus paper titled, "Points to Consider Document: Scientific and Regulatory Considerations for the Analytical Validation of Assays Used in the Qualification of Biomarkers in Biological Matrices."

Once biomarkers are qualified as drug development tools (DDTs) by regulatory entities, such as the US Food and Drug Administration's (FDA) Biomarker Qualification Program within the Center for Drug Evaluation and Research (CDER), supporting information is made publicly available for use by drug development programs, which can result in increased opportunities to improve safety, efficiency and innovation in the drug development process.

The points to consider document outlines PSTC-recommended scientific and regulatory considerations for the analytical validation of assays for fluid-based biomarkers qualified by regulatory agencies for use as DDTs.

"Assays used to measure biomarkers produce critical evidence for both drug development programs and regulatory agencies," explained John-Michael Sauer, PhD, Program Officer of C-Path's Biomarkers Program and PSTC Executive Director. "It's imperative, then, that these assays undergo extensive testing and rigorous analytical validation to ensure accuracy in measurement of the biomarkers being studied, and the ability to generate reliable and consistent results that can be properly analyzed."

"This is the result of collaboration among many biomarker stakeholders, including scientists from the FDA, and contains a complete description of necessary approaches that can be applied to most analytical situations that will be encountered in fluid-based biomarker qualification and can serve as a guide to the analysis of biomarkers in drug development," said Steven Piccoli, PhD, Head of Clinical Biomarkers, Experimental Medicines at GlaxoSmithKline.

Topics discussed in the document include considerations for assay design and technology selection, optimization of pre-analytical factors, core assay performance expectations, and setting minimally acceptable assay performance criteria. It addresses seven key analytical parameters, including figures and examples to aid in assessing the impact of these analytical parameters on assays that will be utilized for biomarker qualification. Two case studies are contained in the document as examples.

The points to consider document represents the efforts of a diverse, dedicated, and expert working group that leveraged current scientific peer-reviewed literature, input from discussion sections at scientific meetings, and public expert opinion to develop valuable consensus on best practice approaches that can be applied to the development, characterization, and validation of assays to support fluid biomarker qualification.

About Critical Path Institute

C-Path (Critical Path Institute) is an independent, nonprofit organization established in 2005 as a public and private partnership. C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established numerous global consortia that currently include over 1,500 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of major pharmaceutical and biotech companies. C-Path is headquartered in Tucson, Arizona, with additional staff in multiple remote locations. For more information, visit www.c-path.org.

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